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APPLICATION NO.	FILING DATE	FIRST NAME	INVENTOR	AT	ATTORNEY DOCKET NO.	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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Offic Action Summary Communication appears on the cover sheet with the correspondenc address - Pari of f Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 10, 16 MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION. A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 10, 16 MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION. Educator of the may be yearlied with one of the provisors of 30 TCR 1.13(6). In no event, however, may a reply be timely filled at a six (8) MONTH's ferm he malling date of the communication. Educator of the may be yearlied with one to the provisors of 30 TCR 1.13(6). In no event, however, may a reply be timely filled at a six (8) MONTH's ferm he malling date of this communication. Educator of the may be yearlied with one to the provisors of villagely and the application to become ABN/DODED(8) U.S. C. \$ 133. Any retyr scene villagely and the provisors of villagely and the provisors of villagely and the communication, men if timely filled, may reduce any service villagely and the provisors of villagely and village and the communication, men if timely filled, may reduce any service of villagely and village and		Application No.	Applicant(s)				
Examiner Ann Y. Lam - The MAILING DATE of this communication appears on the cover sheet with the correspondenc address Peri of I r Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 10.16 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of lines may be available under the provisions of 37 CPR 1.13(b). In re-event, however, may a raply be timely filled the provision of the reply specified above, the maximum shallarly packed will apply and will agree 101 (b) MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of lines may be available under the provisions of 37 CPR 1.13(b). In re-event, however, may a raply be timely filled the provision of the provision of 10 CPR 1.13(b). In re-event, however, may a raply be timely filled the provision of the specified above, the maximum shallarly packed will apply and will agree 101 (b) MONTH's from the mailing date of the communication of the provision of the specified above, the maximum shallarly packed will apply and will agree 101 (b) MONTH's from the mailing date of the communication. 1 Provision of the specified above, the maximum shallarly packed will apply and will agree 101 (b) MONTH's from the mailing date of the communication. 2 Provision of the specification is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disp sition of Claims 4) Claim(s) 1-23 Is/are pending in the application. 4) Claim(s) 1-23 Is/are allowed. 6) Claim(s) 1-31-15 and 21 Is/are rejected. 7) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 6) Claim(s) is/are allowed. 7) Claim(s) is/are allowed. 8) The drawing(s) filed on is/are: all accepted or bloop objected to by the Examiner. 10) The drawing(s) filed on is/are: all accepted or bloop objected to by the Examiner. 10) The drawing(s) filed on is/are: all accepted or bloop objected to by the Examiner. 11) Acknowledgment is made of a claim for foreign priority							
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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
- being anticipated by Lee, 5125,904. Lee discloses a valve body (14) having a lumen therethrough; means (34) for breaking said valve body along a predetermined location; means (16b) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (valve body lumen) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and means (22) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (proximal end of 24) for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

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As to claim 3, Lee discloses a means (22 and 24) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (34) for breaking apart said fluid flow restricting means responsive to applied force; and means (proximal end of 24) for admitting a catheter distal end into said valve.

As to claim 4, the means (22 and 24) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (proximal end of 24) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position, see column 5, lines 62-66.

As to claim 5, said means (22 and 24) for restricting flow includes a flexible, constrictable tube (24) having a lumen therethrough.

As to claim 6, said means (22 and 24) for restricting flow includes means for pinching (22) said flexible tube for constricting said flexible tube lumen.

As to claim 12, Lee discloses a tubular, distal introducer sheath (12) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (34) for preferentially tearing said sheath along said strip; a tubular, flexible, proximal valve sleeve (24) having a proximal region, a distal region, and a lumen therethrough; and a valve body (16) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (34) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (proximal end of 16) for mating to said proximal valve sleeve distal region, see Figure 2, said valve body

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including a pinch member (22) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve, see column 5, lines 62-66.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position, see Figure 2.

As to claim 15, Lee discloses a breakaway distal portion (34) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (16) including two opposed valve body members, at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed members move together relative to each other to reach said closed position, see column 5, lines 62-66, and column 6, lines 9-10, wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position, see column 5, lines 1-2.

As to claim 21, said valve body members (16) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis. (The valve body members (16) are integral with the hinge.)

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2. Claims 1-9, 11-15 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck, 6,083,207. Heck discloses means (212) for breaking said valve body along a predetermined location; means (70, 71) for coupling said valve body to a peel-away sheath for coupling said peel-away sheath lumen to said valve body lumen; means (50) for receiving a compressible valve sleeve having a lumen therethrough for coupling said valve sleeve lumen to said valve body lumen; and means (52) for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through valve and valve sleeve lumen.

As to claim 2, the valve sleeve inherently includes a free end extending past said means for compressing, and further comprising means (206) for receiving a catheter tip within said valve sleeve lumen free end while said means for compressing is compressing said valve sleeve, such that said valve sleeve lumen is substantially occluded by said inserted catheter tip while said catheter tip is inserted.

As to claim 3, Lee discloses a means (52, 20) for reversibly restricting fluid flow from said sheath lumen coupled to said sheath proximal end; means (70, 71) for breaking apart said fluid flow restricting means responsive to applied force; and means (50) for admitting a catheter distal end into said valve.

As to claim 4, the means (52, 20) for reversibly restricting flow has an open position for allowing flow therethrough and a closed position for substantially restricting flow, wherein said means (50) for admitting said catheter distal end includes means for admitting said catheter distal end while said means for restricting flow is in said closed position,.

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As to claim 5, said means (52, 20) for restricting flow includes a flexible, constrictable tube (20) having a lumen therethrough.

As to claim 6, said means (52, 20) for restricting flow includes means (52) for pinching said flexible tube for constricting said flexible tube lumen.

As to claim 7, said means for pinching has at least two portions (26, 28) movable with respect to each other, said two portions having means (52) for accepting and pinching said flexible tube therebetween, said two portions together having an open position and a closed position.

As to claim 8, said movable pinching member portions are hingedly coupled together with at least one hinge, see column 7, lines 33-36, and see Figure 3.

As to claim 9, said sheath has a longitudinal axis and said at least one hinge has an axis substantially parallel with said sheath longitudinal axis and said hinge enables movement of said pinching member portions about said hinge longitudinal axis for pinching said flexible tube in said closed position, see column 7, lines 33-36, and see Figure 3.

As to claim 11, when in said closed position, said pinching members (52) include means for leaving sufficient space in said flexible tube lumen for passage of a guide wire.

As to claim 12, Heck discloses a tubular, distal introducer sheath (20) having a proximal region and a lumen therethrough, said sheath having at least one longitudinal strip (212) for preferentially tearing said sheath along said strip, see column 9, lines 7-9; a tubular, flexible, proximal valve sleeve (medical device, see column 9, lines 18-19)

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having a proximal region, a distal region, and a lumen therethrough; and a valve body (12) having a lumen therethrough and being sealingly coupled to said introducer sheath proximal region, said valve having at least one weakened region (near 94) for preferentially splitting said valve into at least two pieces responsive to an applied breaking force, said valve body having a seat (50) for mating to said proximal valve sleeve distal region, said valve body including a pinch member (52) for pinching said flexible valve sleeve and having a closed position for constricting fluid flow through said valve sleeve and an open position for admitting a catheter inserted through said valve sleeve.

As to claim 13, said flexible valve sleeve includes a free portion proximal of said pinch member for admitting said catheter into said sleeve free portion while said pinch member is in said closed position.

As to claim 14, said valve body pinch member (52) includes a recess therein for allowing passage of a guide wire through said pinch member while said pinch member is in said closed position.

As to claim 15, Lee discloses a breakaway distal portion (20) having a lumen therethrough for receiving said introducer sheath proximal region; and a proximal portion (12) including two opposed valve body members (26, 28), at least one of which is movable relative to the other and having concave surfaces therebetween for receiving a flexible valve sleeve therebetween, said valve body opposed members having an open position and a closed position, wherein said valve body members move apart relative to each other to reach said open position and said valve body opposed

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members move together relative to each other to reach said closed position, see column 7, lines 33-37, and column 8, lines 26-30) wherein said flexible sleeve has a lumen therethrough and said sleeve and sleeve lumen are constricted between said body members in said closed position, such that fluid flow through said sleeve is substantially restricted in said closed position.

As to claim 21, said valve body members (26, 28) are considered pivotally mounted to each other along at least one hinge oriented substantially parallel to said valve body lumen longitudinal axis, see column 7, lines 33-37, and column 8, lines 26-30.

Response to Arguments

Applicant traverses Examiner's assertion in the Restriction requirement that currently no claim is generic. Applicant argues that at least independent claims 1, 3, 12 and 15, along with dependent claims 2, 4-7, 11, 13-14 and 17-20 recite elements that are common to all asserted patentably distinct species of the claimed invention, see page 1, lines 8-9, and page 2, lines 1-2, of Applicant's response.

In response, Examiner partly agrees with Applicant. Examiner hereby withdraws the assertion that currently no claim is generic. However, Examiner asserts, contrary to Applicant, that independent claims 1, 3, 12 and 15, along with independent claims 2, 4-7, 13 and 17-19 recite elements that are common to all asserted patentably distinct species, and thus are generic claims. However, Claims 11, 14 and 20 recite a means for leaving sufficient space, or specifically a recess, in the flexible tube lumen for

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passage of a guide wire; however, this means is not disclosed in the patentably distinct species disclosed in Figure 4. Claim 15 recites that the valve body members have concave surfaces, see lines 5-6 of Claim 15; however, this means is not disclosed in the patentably distinct species disclosed in Figure 4.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

September 6, 2001

ANHTUÁN T. NGUYEN PRIMARY EXAMINER